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Pesticide Products Containing Ethylene Dibromide (EDB); Preliminary Notice of Determination Concluding the Rebuttable Presumption Against Registration; Availability of Position Document 2/3

ENVIRONMENTAL PROTECTION AGENCY

[OPP 30000/25B; PH-FRL 1697-1]

Pesticide Products Containing Ethylene Dibromide (EDB) Preliminary Notice of Determination Concluding the Rebuttable Presumption Against Registration; Notice of Availability of Position Document 2/3

AGENCY: Environmental Protection Agency (EPA).

ACTION: Preliminary Notice of Determination and Availability of Position Document.

SUMMARY: On December 14, 1977, the Environmental Protection Agency issued a Notice of Rebuttable Presumption against Registration (RPAR) and continued registration of pesticide products containing ethylene dibromide (EDB). After reviewing all available information, the Agency has concluded that the presumptions for oncogenicity, mutagenicity and reproductive disorders have not been rebutted. After evaluating the human health risks and the economic benefits, the Agency has reached a preliminary decision to immediately cancel use of EDB on stored grain, flour mill machinery, and felled logs; to cancel use of EDB for post-harvest fumigation of citrus and tropical fruits effective July 1, 1983; to allow continued but restricted use for fumigation of soil, stored beehives, stored furniture and clothing, and nursery stock; and to defer a decision on use of EDB for control of termites, but require use restrictions in the interim.

DATE: Written comments should be submitted on or before January 9, 1981.

ADDRESS COMMENTS TO: Document Control Office, Environmental Protection Agency, Office of Pesticides and Toxic Substances (TS-793), Room E-447, 401 M St. SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Richard Johnson, Project Manager, Special Pesticide Review Division, Office of Pesticide Programs (TS-791), Environmental Protection Agency, Rm 709, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202, (703-557-7451). Three copies of the comments should be submitted bearing the identifying notation [OPP 30000/25B].

SUPPLEMENTARY INFORMATION: The Preliminary Notice of Determination and the EDB Position Document 2/3 (PD 2/3) set forth in detail the reasons for these proposed regulatory actions. As required by FIFRA, copies of this Preliminary Notice of determination and the Position Document are being transmitted to the Secretary of Agriculture and the Scientific Advisory Panel for comment; these documents are also being provided to the affected registrants and applicants for registration. Other interested persons may receive a copy of the PD 2/3 by contacting Richard Johnson, Project Manager, at the address given.

I. Introduction

On December 14, 1977, the Agency issued a Notice of Rebuttable Presumption against Registration (RPAR) and continued registration of pesticide products containing ethylene dibromide (EDB), a soil and commodity fumigant. This action, published in the **Federal Register** [42 FR 63134], initiated the Agency's public review of the risks and benefits of EDB. The rebuttable presumption was issued on the basis of oncogenicity, mutagenicity and reproductive disorders. The Agency also requested registrants and other interested parties to submit data on these effects: acute toxicity to humans, teratogenicity and the levels of EDB to which humans may be exposed.

This notice constitutes the Agency's Notice of Preliminary Determination pursuant to 40 CFR 162.11(a)(5). The determination is not yet final. Final determination is pending following external review by the United States Department of Agriculture (USDA) and the Scientific Advisory Panel, pursuant to sec. 6(b) and 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended. The action does not become final until the Ageny has evaluated the comments of these reviewers and issued a final notice.

In summary, the Agency has determined that EDB continues to meet or exceed the risk criteria outlined in 40 CFR 162.11 for oncogenicity, mutagenic damage and reproductive disorders. The risks that EDB poses to certain exposed groups are significant and require the Agency to consider whether these risks can be reduced. The Agency has considered benefits information including that submitted by registrants, interested persons, and the USDA, and has analyzed the economic, social and environmental benefits of the uses of EDB. The Agency has weighed risks and benefits together to determine whether the risks of each EDB use are warranted by the benefits of that use. In weighing risks and benefits, the Agency considered what risk reductions could be achieved and how risk reduction measures would affect the benefits of the use.

The Agency has determined that the risks to human health of certain uses of EDB are greater than the social, economic, and environmental benefits of these uses, and that risk reduction measures cannot reduce the risks to an acceptable level. Accordingly, the Agency proposes to initiate action to immediately cancel or deny registrations for all such uses, including fumigation of stored grains, spot fumigation of grain milling machinery, and fumigation of felled logs, and to cancel post-harvest quarantine fumigation of citrus, imported tropical fruits and vegetables on July 1, 1983. As required by FIFRA, the Agency has evaluated the impact of these actions on the agricultural economy. This evaluation is summarized later in this notice, and is discussed in detail in Position Document 2/3.

For certain other uses of EDB, including preplant soil fumigation, fumigation of beehive supers, vault fumigation of stored clothing and furniture, and Japanese Beetle control, the Agency has determined that the risks of EDB uses are greater than the social, economic, and environmental benefits of these uses, unless the terms and conditions of registration are amended to reduce risk. Accordingly, the Agency is proposing to initiate action to cancel or deny registration for all such uses unless the terms and conditions of registration are amended. These amendments include classifying EDB for restricted use by certified applicators only, requiring aplicators to wear respirators and protective clothing, and requiring that signs be posted on the treated site to warn persons not to enter the area for a specified length of time after EDB treatment. To better determine the exposure and risks associated with the preplant use of EDB, the Agency is also requiring a study of EDB's potential to leach from soil into groundwater and another study to determine whether detectable residues of EDB appear in crops. Additionally, food residue data will be required for beehive super fumigation.

The Agency has determined that these amendments to the terms and conditions of registration will significantly reduce risk, and that these risk reductions can be achieved without a significant impact on the benefits of the uses.

Finally, a decision on the use of EDB to control termites will be deferred until a comprehensive risk-benefit analysis of all termiticides is performed. In the interim, the Agency proposes to amend the terms and conditions of registration to reduce exposure to applicators and other persons in the immediate area, and to require exposure data.

The remainder of this Notice and the Agency's Position Document (PD 2/3) set forth in detail the Agency analysis of

comments submitted during the rebuttal phase of the EDB RPAR, and the Agency's reasons and factual bases for the regulatory actions it proposes. The Notice is organized into four units. Unit I is this introduction. Unit II, titled "Legal Background," is a general discussion of the regulatory framework within which these actions are taken. Unit III sets forth the Agency's determinations concluding the EDB RPAR and initiating the regulatory actions which result from these determinations. Together with the Position Document 2/3, this unit also sets forth the bases for these determinations. Unit IV, titled "Procedural Matters," briefly discusses the procedures which will be followed to implement the regulatory actions which the Agency is proposing in this Notice.

II. Legal Background

To obtain a registration for a pesticide under FIFRA, a manufacturer must demonstrate that the pesticide satisfies the statutory standard for registration. That standard requires, among other things, that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment". This is defined as "any unreasonable risk to a man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA sec. 2(bb)].

In effect, the standard requires a finding that the benefits of each use of the pesticide exceed the risks of that use, when the pesticide is used in accordance with commonly recognized practices. The burden of proving that a pesticide satisfies the registration standard is on the proponent(s) of registration and continues as long as the registration remains in effect. Under sec. 6 of FIFRA, the Administrator is required to cancel the registration of a pesticide or amend the terms and conditions of registration whenever he determines that the pesticide no longer satisfies the statutory standard for registration.

The Agency created the RPAR process to identify pesticide uses which may not satisfy the statutory standard for registration. This process provides the public with an informal procedure to gather and evaluate information about the risks and benefits of these uses. The regulations governing the RPAR process are set forth in 40 CFR 162.11, which provides that a rebuttable presumption shall arise if a pesticide meets or exceeds any of the specified risk criteria.

The Agency announces that an RPAR has arisen by publishing a notice of this determination in the **Federal Register**. After an RPAR is issued, registrants and other interested persons are invited to review the data upon which the presumption is based and to submit data and information to rebut the presumption. Respondents may rebut the presumption of risk by showing that use of the pesticide is not likely to result in any significant exposure to humans or to the environment with regard to the adverse effects in question under 40 CFR 162.11(a)(4). In addition to submitting evidence to rebut the risk presumption, respondents may submit evidence as to whether the economic, social, and environmental benefits of the use of the pesticide outweigh the risks.

The regulations require the Agency to conclude an RPAR by issuing a Notice of Determination in which the Agency states and explains its position on whether or not the risk presumptions have been rebutted. If the Agency determines that a presumption is not rebutted, it will then consider information relating to the social, economic and environmental costs and benefits which registrants have submitted, and other benefits information known to the Agency.

After weighing the risks and the benefits of a pesticide use, the Administrator may conclude the RPAR process by issuing a notice of intent to cancel or deny registration pursuant to FIFRA sec. 6(b)(1) and sec. 3(c)(6), or by issuing a notice of intent to hold a hearing pursuant to sec. 6(b)(2) of FIFRA to determine if the registrations should be cancelled and applications for registration denied.

In determining if a pesticide's use poses risks which are greater than its benefits, the Agency considers possible changes to the terms and conditions of registration which can reduce risks, and their impacts on the benefits of the use. Among the risks reduction measures short of cancellation which are available to the Agency are changes on the pesticide's label in the directions for use and also classification of the pesticide for restricted use under FIFRA sec. 3(d).

FIFRA sec. 6(b) requires the Agency to submit notices issued pursuant to sec. 6 to the Secretary of Agriculture with an analysis of the impact of the proposed action on the agricultural economy. The Agency is required to submit these documents to the Secretary at least 60 days before sending the notice to registrants or making the notice public. If the Secretary of Agriculture comments in writing within 30 days of receiving the notice, the Agency is required to publish the Secretary's comments and the Administrator's response with the notice. FIFRA sec. 25(d) requires the Administrator to submit sec. 6 notices to the SAP for comment on the impact of the proposed action on health and the environment.

Although not required to do so by FIFRA, the Agency also makes copies of the Position Document available to registrants and other interested persons when the decision documents are transmitted for formal external review. The Agency does this by publishing a notice of availability in the **Federal Register** or by other means. Registrants and other interested persons are allowed the same 30-day period to comment that the statute provides for receipt of comments from the Secretary of Agriculture and the Scientific Advisory Panel.

After these external review procedures are completed, the Agency makes any changes in the proposed action which are deemed appropriate as a result of the comments received. The Agency proceeds to implement the desired regulatory action by preparing appropriate documents and releasing them in the manner prescribed by the statute and by the Agency's rules.

III. Determination and Initiation of Regulatory Action

The Agency has considered information on the risks from the uses of EDB, including information submitted by registrants and other interested persons in rebuttal to the EDB RPAR. The Agency has also considered information on the social, economic, and environmental benefits of the uses of EDB, including benefits information submitted by registrants and other interested persons in conjunction with their rebuttal submissions, and information from the USDA.

The Agency's assessment of the risks and benefits of the uses of EDB, its conclusions or determinations of whether or not any uses of EDB cause unreasonable adverse effects on the environment, and its determination of whether or not amendments in terms or conditions of registration reduce risks sufficiently to eliminate any unreasonable adverse effects are set forth in detail in the Position Document. This Position Document is hereby adopted by the Agency as its statement of reasons for the determinations and actions announced in this Notice, and as its analysis of the impacts of the proposed regulatory actions on the agricultural economy. For the reasons summarized below and developed in detail in the Position Document, the Determinations of the Agency with respect to EDB are as follows:

A. Determination of Risk

The EDB RPAR was based on information indicating that EDB posed three risks to humans or the environment: oncogenicity, mutagenicity and reproductive disorders. As developed fully in PD 2/3, the Agency has determined that the information submitted to rebut these risk criteria are insufficient to rebut the presumption against EDB for these effects.

1. *Oncogenicity.* In issuing the RPAR, the Agency relied on evidence of oncogenicity reported in a study sponsored by the National Cancer Institute (NCI) (Weisburger, 1977) that showed a statistically significant increase in the incidence of squamous cell carcinomas of the forestomach in both rats and mice as compared to the controls. It was determined that EDB causes a significant increase in the incidence of gastric carcinomas in both sexes of rats and mice. Metastases of these tumors were reported; the tumor rates appear to be high and the differences are highly significant.

Six respondents addressed rebuttal comments to the oncogenicity criterion. The Agency has divided these rebuttals into two broad categories: those which address uncertainties in extrapolating to man from the laboratory studies conducted on animals, and those studies which investigate the health of workers occupationally exposed to EDB.

In the first category, related to animal oncogenicity, rebutters claimed that: intubation of EDB into the animals could not easily be extrapolated to inhalation, the primary exposure route of humans; massive does of EDB masked true effect levels and metabolic and detoxification processes; humans do not have a forestomach, where most of the tumors occurred in animals; and irritation at the site of intubation caused the oncogenic response.

These rebuttals were addressed as follows: To the first, human exposures to EDB occur both from its inhalation and its presence in the human diet. A new study by Midwest Research Institute (MRI), demonstrating an increase in the incidence of tumors in a group of animals exposed by inhalation to 20 ppm of EDB alone, was used to quantify the cancer risks to persons exposed to EDB via inhalation. A very recent study by NCI provides additional support for the Agency's analysis. To the second, the use of maximum tolerated dose (mtd) ½ mtd is now accepted by the Agency, the MRI study demonstrated cancer at low doses, and the Agency supports a no-threshold concept of cancer induction. To the third, tumor sites differ depending on many factors; thus the absence of a forestomach does not make humans immune to the carcinogenic effects of EDB. To the fourth, the Agency has concluded that there is no correlation between carcinogenic potency of the agent and the degree of irritant injury produced.

Regarding the second category of comments, one rebutter responded with three studies investigating the health of workers exposed to EDB. The Agency found only one of these studies to be technically acceptable. This particular study demonstrated a slight increase in the incidence of stomach cancer and deaths due to all causes; however, this increase cannot be solely attributed to EDB exposure, because workers were also exposed to other chemicals.

2. *Mutagenicity.* In the RPAR Notice the Agency evaluated all of the available studies on the mutagenic potency of EDB and concluded that EDB is positive in both prokaryotic (microbial) and eukaryotic (higher forms including mammals) organisms for point (gene) mutational effects, with and without mammalian metabolic activation. Four respondents submitted rebuttals specific to the presumption of the mutgenic risk of EDB, including general arguments about the mutagenicity testing system used and specific statements about the studies reviewed in PD–1. The general comments addressed the limitations of the test systems used and the validity of specific studies. The Agency's response to these general comments is that the methodology currently used in mutagenesis assay studies has been generally accepted on theoretical grounds and offers the only means to predict adverse genetic effects in humans.

3. *Reproductive Disorders.* In the RPAR Notice the Agency cited several studies in bulls and rodents which established that EDB could adverely affect mammalian reproductive development by interfering with the production of male gametes and the development of embryos. Adverse effects in hen egg production were also noted.

No rebuttals seriously questioned the validity of the animal reproductive studies evaluated in the RPAR Notice. However, all respondents noted the reversibility of the effects at all but the highest doses in hens and the general reversibility of effects in bulls following cessation of dosing. Respondents argued the the effects produced in hens are probably specific to the hen and that the bull is specifically sensitive to EDB. Generally, the rebuttals disputed the significance which the Agency placed on the animal studies. More specifically, the rebuttals argued that the reproductive disorders observed in bulls orally administrated EDB cannot be used to determine a safe level of human exposure to inhaled EDB. The basis for this argument was that the bull is unusually sensitive to reproductive disorders. In addition, the rebuttals contended that it is inappropriate to determine a margin of safety by comparing levels to which humans are exposed via inhalation with the amount of EDB to which bulls were exposed orally.

The Agency concluded that these rebuttals are not valid and do not change the Agency's position. In the absence of adequate human data, the Agency's normal policy is to used data from the most sensitive species which in this case is the bull. This procedure is dictated by regulatory prudence. In the absence of adequate human data it is reasonable to assume that man is at least as sensitive as the most sensitive species for which data are available. The question of asssuming that all EDB inhaled is retained is basically similar to the question of the most sensitive species: In the absence of adequate data it is prudent to assume that the worst case applies (e.g., all inhaled EDB is retained). Thus, the Agency concludes that it is in the interest of public health to use the results from the reproductive studies on bulls to evaluate the reproductive risks to humans. In further support of this assumption, the Agency has recently completed an inhalation study on rats (Short et al., 1976) which demonstrates that this exposure route also causes deleterious effects upon reproductive tissues.

4. *New Studies.* Since the issuance of the RPAR Notice, studies of EDB's oncogenic potential by the Midwest Research Institute (Wong, 1979) and the National Cancer Institute (NCI, 1980) have been completed. These studies demonstrate that inhaled EDB produces a statistically significant increase in tumors of several sites in exposed animals.

The Agency has also reviewed new studies which support the position presented in the RPAR notice that EDB causes point mutations and primary DNA damage. The Agency's reevaluation of one study (Ehrenberg et al., 1979) further indicates that EDB poses the potential risk of chromosome-damaging effects to humans.

The Agency has reviewed two epidemiology studies submitted in rebuttal to the reproductive risk criterion (Wong, 1977; Ter Haar, 1978). Both studies, examined in detail in the PD 2/3, were rejected on the basis of numerous technical flaws. At the same

time, the Agency sponsored two reproductive studies: a human epidemiology study (Griffith et al., 1978) and an animal exposure study in rats (Short et al., 1976). Discussions and references for these studies are presented in the PD 2/3. The Agency-sponsored human epidemiology study is being re-evaluated, although it is considered of limited significance because it consisted of a very small number of exposed individuals. However, the reproductive study of rats exposed to EDB via inhalation suggests that a no observable effect level (NOEL) for atrophy of the prostate is 19 ppm in the rat.

5. *Exposure Analyses.* After evaluating the rebuttal submissions, the Agency extensively reviewed all human exposures from pesticidal uses of EDB. Human dietary exposures were examined for the following EDB-treated commodities: grain and flour products; fruits, nuts or vegetables; and commodities grown in EDB-treated soils. Inhalation and dermal exposures were examined for agricultural workers during soil fumigation, and for agricultural workers who fumigate stored grains, citrus, and tropical fruits. In addition, exposures of workers in mills processing grains into flour, those handling treated fruits and vegetables, and people in the vicinity of these processes were discussed. The lower volume uses of EDB, such as termite control, forestry uses, vault fumigation of clothes and furniture, application to sod, grasses, and plants, and production of honey where beehive supers have been fumigated were all examined for possible health effects from exposure to EDB. The Agency found residues of EDB in flour and bread, on fruits and vegetables, in air inhaled by exposed workers, and from dermal contact with treated commodities.

6. *Conclusions on Risk.* Using these exposure data, Agency scientists developed lifetime cancer risk estimates by extrapolating from the cancer incidence observed in exposed animals. The range of cancer risk was from moderate (10^{-5}) to very high (10^{-1}) depending upon the persons exposed and the routes of exposure. In addition, from the accumulation of evidence demonstrating mutagenic activity in a variety of organisms, the Agency concludes that EDB presents a risk of inducing mutagenic damage to humans.

Reproductive studies have demonstrated effects on animals and consequently the Agency concludes that exposure to EDB also poses risks of reproductive disorders in exposed human's.

In sum, the Agency concludes that EDB poses risks of oncogenicity, mutagenicity and reproductive disorders to applicators, who may be exposed during application both dermally and via inhalation, and to the general population, exposed to residues of EDB in treated commodities and potentially in drinking water. These risks are of sufficient magnitude to require the Agency to determine whether the uses of EDB offer offsetting social, economic, or evironmental benefits.

B. Determinations of Benefits

The uses of EDB which are subject to this RPAR include: fumigation of stored grain to prevent insect infestations; fumigation of citrus, tropical fruits and vegetables to prevent spread of fruit flies; spot fumigation of grain milling machinery to prevent insect infestations; preplant soil fumigation to control nematodes; spraying of felled logs to control bark beetles; fumigation for subterranean and drywood termite control; fumigation of beehive supers and honeycombs during storage to control greater wax moths; fumigation of stored furniture and clothing as a control measure against moths and other insects; and fumigation of plants, soil and grass sod as a quarantine measure against Japanese beetles.

1. *Fumigation of Stored Grain.* EDB is used in combination with ethylene dichloride and carbon tetrachloride to control insects in stored grain. About 2 percent of the grain produced in this country is treated annually with fumigants containing EDB.

The most likely alternative to EDB-containing mixtures is an 80 percent/20 percent mixture of carbon tetrachloride and carbon disulfide at on-farm storage facilities, and aluminum phosphide at off-farm storage centers. Fumigation costs would actually decline if EDB became unavailable and were replaced with these alternatives. The Agency estimates a $500,000 to $2,260,000 annual savings from use of the alternatives to EDB.

2. *Quarantine Fumigation of Citrus, Tropical Fruits and Miscellaneous Fruits and Vegetables.* USDA's Animal and Plant Health Inspection Service (APHIS) requires use of EDB to destroy certain fruit flies. Japan also requires that all fresh grapefruit imported from the U.S. be treated with EDB. In 1977, approximately 83,500 pounds active ingredient of EDB were used in the APHIS program.

There are currently no registered chemical alternatives to EDB for quarantine purposes. Vapor heat and cold storage can control flies as effectively as EDB, but often result in fruit damage.

Another method, gamma irradiation, shows promise as a substitute; however, the Food and Drug Administration, which is responsible for evaluating use of this method on food, has not yet completed its review of the use of irradiation on fruits and vegetables.

The overall impact of EDB cancellation on the APHIS Quarantine Program is an estimated increase of $538,900 in annual treatment costs and an estimated decrease of $24,800,800 per year in the value of production.

Under current trade agreements, the cancellation of EDB use in the APHIS quarantine programs would have an adverse impact, roughly estimated at $18.4 million, on the U.S. balance of payments with Japan.

3. *Spot Fumigation of Grain Milling Machinery.* EDB has been used for over 20 years as a spot fumigant to control insect infestations in flour milling equipment. Currently, an estimated 465,000 pounds of EDB active ingredient are used annually for this purpose. A 70 percent EDB/30 percent methyl bromide combination is commonly used. The only alternative spot fumigant that does not contain EDB is a mixture of 75 percent ethylene dichloride and 25 percent carbon tetrachloride. However, the dosage required for this pesticide is so large that it would result in clogging of machinery; as a result, the milling industry does not consider this mixture to be a viable substitute. The only viable alternative to spot fumigation is general fumigation of the entire mill space. Methyl bromide and aluminum phosphid are currently the two most commonly used general space fumigants.

The principal economic impact of the cancellation of EDB for this use would be the increased cost of substituting general space fumigation of the entire mill for the current practice of spot fumigation of individual pieces of milling equipment. Based on the relative cost of the present versus the projected systems, the most likely increase in total annual costs would be $3,800,000 in the wheat, durum, and rye milling industries and $800,000 in the dry corn milling industry.

If five rather than four general fumigations are necessary per year, wheat and rye mill costs would increase $6.4 million annually, and corn mill costs would increase $1.3 million annually.

4. *Preplant Soil Fumigation*—a. *Tobacco.* EDB is used to control root-knot, root lesion, and stunt nematodes on flue-cured tobacco in Florida, Georgia, North Carolina, South Carolina and Virginia. About 2.1 million pounds

of EDB as an active ingredient were used in 1977.

Registered chemicals that may be alternatives to EDB include other fumigants (DD and Telone II), multi-purpose fumigants (Telone C–17, DD/Pic, Vorlex), and non-fumigants (ethoprop, fensulfothion, carbofuran and oxamyl). Growers switching from EDB to other fumigants or from multi-purpose formulations containing EDB to other multi-purpose fumigants would not experience any significant change in yield regardless of nematode population levels; however, the alternatives to EDB are more expensive. If EDB were to become unavailable, tobacco growers would pay approximately $1.2 million more for control than they now pay using EDB.

b. *Pineapple.* All commercial U.S. pineapple production is located in Hawaii, and all Hawaiian pineapple acreage must be treated with nematicides. Damage is caused either by the root-knot nematode or the reniform nematode. Approximately 572,400 pounds of EDB are used annually for nematode control in Hawaiian pineapple fields. The alternative to EDB is DBCP, which is applied in combination with either DD or Telone. EDB is used on the approximately 11,500 acres where high soil moisture makes it the most desirable nematicide to use.

The net present cost of the combination of these economic impacts, over the entire production cycle following removal of EDB (a 5½ year period), is estimated to be $5.3 million (using a 7 per cent discount rate). In the long run, approximately $1.5 million in additional costs per year would be paid by Hawaiian pineapple growers until a satisfactory substitute for EDB is registered.

c. *Citrus.* EDB is registered for preplant use in fruit tree planting sites, including citrus groves. Target pests are the citrus nematode and the burrowing nematode. EDB use in citrus growing (preplant) has been estimated at 20,000 pounds active ingredient per year, treating less than one percent of new citrus acreage planted annually. The most viable alternatives to EDB for preplant citrus use are DD and Telone.

A second use of EDB in citrus is barrier establishment and maintenance to control the burrowing nematode in Florida. About 250,000 pounds active ingredient are annually chisel-injected in barrier zones.

Economic impacts from cancellation of EDB for use on citrus are expected to be minimal. The limited use of EDB in preplant application indicates that the total cost increases to affected growers will be only $3,500 per year; however, in the burrowing nematode control program, use of alternatives will increase grower costs from $25,000 to $63,000 per year, depending on the alternative nematicide chosen.

d. *Peaches.* EDB is used as a preplant nematicide for peaches. Prior to the suspension of DBCP, approximately 170,000 pounds of EDB active ingredient were used annually, and DBCP was used to treat an additional 8,325 acres annually. If the suspension of DBCP becomes a permanent cancellation, EDB would be the preferred chemical on these acres.

Registered alternatives to EDB for use in peach orchards are numerous, and include DBCP (suspended), DD, Telone, Vorlex, methyl bromide, zinophos, and chloropicrin. The major alternatives (DBCP, DD, and Telone) are as effective as EDB.

If DBCP use is allowed to continue on peaches, increased grower costs would range between $20,300 and $118,180 annually depending on the alternative chemical of choice. However, if DBCP is permanently cancelled and EDB is assumed to be the preferred chemical on 10,325 acres, added grower costs from EDB cancellation would range from $378,700 to $610,100 annually. At industry level, the increased costs are not significant under either scenario (with and without DBCP).

e. *Peanuts.* About 17 percent of peanut acreage in the major U.S. peanut-producing regions is treated with EDB, resulting in annual EDB usage of approximately 4.2 million pounds of the active ingredient.

There are several registered alternatives to EDB for use on peanuts, although none are as effective. The major liquid fumigant alternatives are Telone II and DD. Viable granular alternatives are Furadan, Dasanit, Mocap, Nemacur, and Temik, which are all applied at planting. All of these alternatives are more expensive than EDB. It is estimated that substituting one of the several alternatives for EDB would increase control costs to peanut growers by approximately $2.5 million per year.

More important than the increased control costs is the decreased value of production which would result from the cancellation of EDB. Yield losses would reduce producers' revenues by $11 million per year in addition to the $2.5 million per year increase in control costs. Government price support programs would probably prevent these losses from influencing consumer prices, however.

f. *Cotton.* EDB is registered for use throughout the cotton belt. An estimated 721,800 pounds were used in 1977, primarily to control the root-knot nematode. However, since that time, the suspension of DBCP may have increased usage to 1.6 million pounds annually. Telone II and DD remain as viable alternatives, and are equally effective under good soil conditions.

The only economic impact expected from cancellation of EDB would be an increase in cost of control of $435,700 per year. When compared to the approximate $3 billion value of the U.S. annual cotton crop, this increase is negligible.

g. *Vegetables.* Approximately 180,000 acres of various vegetables are treated by preplant soil fumigation with EDB to control nematodes. An estimated 4.7 million pounds active ingredient of EDB are used annually.

Alternatives to EDB (Vorlex, DD, and Telone II) are considered equally effective. The loss of EDB would result in increased pest control costs to vegetable producers of $3.8 million per year. There would be no loss in vegetable production due to the cancellation of EDB. Given a producer value of about $3 billion, the increased costs of the alternative fumigants would not have a significant impact on prices of these vegetables.

5. *Fumigation of Felled Logs.* Several bark beetle species in the West attack coniferous trees and cause demage which can be reduced through the use of EDB. The alternatives are lindane and endosulfan. However, lindane is not being considered a viable alternative because it is in RPAR review. Limited information indicates that endosulfan is less effective than EDB. Nonchemical controls are effective, but during pest epidemics chemical control may also be needed.

The extent to which EDB has been used for forestry purposes is not sufficient to appreciably affect commercial timber harvests. Rather, EDB is generally used where bark beetle damage may have aesthetic impacts. Cost of control could be reduced by as much as $36,000 per year if endosulfan were to replace EDB; however, endosulfan may not be as effective as EDB.

6. *Termite Control.* EDB is the only pesticide registered by EPA as a fumigant for subterranean termite control. EDB is also state-registered in California for the control of drywood termites. Alternatives include aldrin, dieldrin, menthyl bromide, chlordane and heptachlor for subterranean termites, and pentachlorophenol (an RPAR chemical), methyl bromide, silica aerogel and hydrogen cyanide for drywood termites. Estimates of EDB use

vary from approximately 11,500 to 27,600 pounds of the active ingredient per year.

Economic impact data on the use of EDB and alternative termiticides are limited; therefore, the magnitude of user, market, and consumer impacts cannot be precisely identified. Because the current use of EDB is small relative to other insecticides, overall impacts should be minor. There are no known chemical alternatives for homeowners in the southeast and southwest. The only known solution is this case is removal of the infested wood, and rebuilding.

7. *Fumigation of Stored Beehive Supers and Honeycombs.* Honeycombs being stored between honey producing seasons are fumigated with EDB to control the larvae of the greater wax moth (GWM), which damages the comb bases held by hive supers. Alternatives to EDB for this use are paradichlorobenzene (PDB) and carbon dioxide. In the North, cold weather is a natural control. Paradichlorobenzene is more practical to use than carbon dioxide, as the latter requires elaborate monitoring equipment to ensure effectiveness and safety for the user. Paradichlorobenzene is somewhat less effective than EDB because it does not provide control of the egg stage of the GWM.

The use of PDB to replace EDB in the treatment of honeycombs will increase beekeeping costs by about $3.7 million annually. Further, with PBD and CO_2 there would be 7 additional treatments needed per super per year. Using the best alternative, PDB, it is estimated that the volume of marketable honey would be reduced 20 percent in a super previously treated with EDB. The total quantity of domestic honey would thus be reduced by 6.67 percent. The annual loss to beekeepers would be 12.7 million pounds, valued at $6.5 million. In addition to these economic impacts, there will probably be some losses attributable to the reduced pollination service which bees provide. It is impossible to estimate the impact on pollination which could result from the cancellation of EDB.

8. *Fumigation of Stored Clothing and Furniture.* Two products containing 5 percent EDB are registered for use in vault fumigation to control insects, including clothes moths, which invade clothing and furniture. The fumigant evaporates and the gaseous fumes fill the vault to penetrate items being treated.

Four alternatives to EDB were found for this use. The first is a mixture of carbon tetrachloride and ethylene dichloride. Because carbon tetrachloride is undergoing RPAR review, this alternative is not considered fully viable. The second registered alternative is chloropicrin. It is a disagreeable material to work with, but this property tends to discourage mishandling and exposure. Methyl bromide is the third alternative. Extreme care must be exercised before applying methyl bromide, because it reacts with a number of organic materials to produce foul-smelling odors.

The fourth chemical registered for this site/pest combination is sulfuryl fluoride. This chemical, like methyl bromide, is released as a gas through copper tubing from a pressure tank into the structure being fumigated. The economic impacts of ending EDB use in vault fumigation were not evaluated but are expected to be small.

9. *Fumigation of Quarantined Plants, Soil and Grass Sod.* The Japanese Beetle Domestic Quarantine program (7 CFR 301.48) requires the treatment of specific regulated articles moved from an infested area into any other area. The specific articles include grass sod, bare root plants, plants balled or in containers, and potting and bench soil. Ethylene dibromide #440 (20 percent EDB), miscible ethylene dibromide #434 (2.5 percent EDB), and methyl bromide are authorized fumigants for regulated articles to control the Japanese beetle. Chlordane has been cancelled for all uses other than structural termite control and dipping the roots and tops of non-food use plants. Therefore, chlordane is limited to only some uses. Methyl bromide is thus the single alternative for all use sites. Cost estimates were not made for the various uses, but the impact is expected to be small.

C. Determinations of Unreasonable Adverse Effects

For the reasons set forth in detail in the Position Document 2/3, the Agency makes the following determinations about unreasonable adverse effects resulting from the uses of EDB.

The Agency has determined that the risks arising from uses of EDB for fumigation of stored grains, spot fumigation of grain milling machinery, and fumigation of felled logs are greater than the social, economic, and environmental benefits. The Agency has determined that these uses of EDB cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practices, and that the labeling of EDB products will not comply with the provisions of FIFRA. Accordingly, the Agency proposes to initiate action to immediately cancel registrations and deny applications for registration for fumigation of stored grain, spot fumigation of grain milling machinery and fumigation of felled logs. For these uses, the Agency has evaluated all feasible actions short of outright cancellation and has determined that immediate cancellation for these uses is the only means to adequately and effectively reduce the health risks of applicators and the general public. The Agency has determined that the cancellation and denial or registrations of these uses of EDB will not have a significant impact on the production and prices of agricultural commodities, retail food prices and other segments of the agricultural economy.

The Agency has also determined that the risks arising from the use of EDB in quarantine fumigation of citrus, tropical fruits, and vegetables are greater than the social, economic and environmental benefits. The Agency has determined that this use of EDB causes unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practices, and that the labeling of EDB products will not comply with the provisions of FIFRA. Therefore, the Agency proposes to cancel EDB registrations and deny applications for EDB registrations for quarantine fumigation of citrus, tropical fruits and vegetables, effective July 1, 1983. This phase-out period is being proposed to allow time for the development and implementation of efficacious alternative treatment methods. In the interim, the Agency will require that specific actions be taken to reduce the exposures of workers at fumigation centers and citrus warehouses. The Agency has determined that these actions can be implemented without significantly affecting the benefits. Unless these interim changes in the terms and conditions of registration described in subpart E. are accomplished, the risks arising from EDB use in quarantine fumigation of citrus, tropical fruits, and vegetables will generally cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practices, and that the labeling of EDB products will not comply with the provisions of FIFRA. It should be emphasized that the Agency believes that, in the long run, measures short of outright cancellation will not reduce the risks sufficiently to alter the conclusion that the use of EDB for quarantine fumigation of citrus, tropical fruits, and vegetables poses unreasonable adverse effects on the environment. The Agency's decision on

the use of EDB in quarantine fumigation will become effective in the Final RPAR Determination and Notice unless a hearing request is made within the statutory 30-day period.

The Agency has further determined that the risks of EDB from its use in preplant soil fumigation, fumigation of beehives and supers, vault fumigation, and Japanese Beetle control are greater than the social, economic, and environmental benefits of these uses unless risk reductions are accomplished. Accordingly, the Agency proposes to initiate actions to cancel or deny registration for these uses unless the terms and conditions of registration are amended, as described in subpart E. The Agency has determined that these amendments to the terms and conditions of registration will significantly reduce risk and that these risk reductions can be achieved without significant impacts on the benefits of the use. These stricter label requirements will not have a significant impact on production and prices of agricultural commodities. The Agency has determined that, unless these amendments in the terms and conditions of registration are accomplished, the uses of EDB in preplant soil fumigation, beehive supers, vault fumigation and Japanese Beetle control will generally cause unreasonable adverse effects on the environment, when used in accordance with commonly recognized practices, and that the labeling of EDB products will not comply with the provisions of FIFRA.

Based on currently available information, the Agency has determined that the risks posed by the use of EDB for control of termites exceed the economic, social, and environmental benefits for this use, unless risk reductions are accomplished by modifying the terms and conditions of registration as described below in subpart E. In the Agency's judgment, these modifications to the terms and conditions of registration will significantly reduce the risks and will not have a major impact on the benefits of this use of EDB. The Agency has concluded on a preliminary basis that without these proposed registration changes, the use of EDB for termite control will generally cause unreasonable adverse effects on the environment when used in accordance with generally recognized practice, and that the labeling of EDB products will not generally comply with the provisions of FIFRA. This decision on the use of EDB for the control of termites will remain in effect until the Agency has reviewed all termite pesticides and has implemented any necessary further regulatory actions.

D. Other Determinations

The Agency has determined that registrants of EDB products must submit additional data pursuant to FIFRA Section 3(c)(2)(B) with respect to certain uses of this pesticide.

1. *Preplant Soil Fumigation.* The Agency will require that data be submitted in order to set a tolerance for residues of EDB in or on food crops grown in EDB-fumigated soils. The Agency also proposes to require that a study be undertaken by the registrant(s) to determine the potential for EDB to leach into groundwater or drinking water supplies.

2. *Fumigation of Beehives and Supers.* Registrants will be required to measure the air levels to which applicators are exposed, to survey the approximate number of applicators for this use, and to conduct a residue study on fumigated supers and honeycombs to determine whether detectable residues of EDB occur in honey.

3. *Vault Fumigation of Stored Clothing and Furniture; and Japanese Beetle Control.* For these uses, registrants will be required to conduct a monitoring study of the levels of EDB to which applicators are exposed before, during and after application. Registrants must also survey the approximate number of vault fumigation centers, the number of applicators involved and the amount of EDB applied annually for this use.

4. *Termite Control.* To provide data for use in a risk/benefit analysis planned for all pesticides used for control of termites, the Agency will require EDB registrants to conduct air monitoring studies which measure air concentrations to which applicators and other persons (such as homeowners) are exposed indoors. Registrants will also be required to report the approximate number of applicators using EDB for termite control, the amount of formulation sold annually, and the frequency of use of EDB by applicators.

E. Initiation of Regulatory Action

Based upon the determinations summarized in this Notice and set out in detail in the PD 2/3, the Agency proposes to initiate these regulatory actions:

1. Immediate cancellation and denial of registration of EDB products for use in grain storage fumigation, spot fumigation of grain milling machinery, and fumigation of felled logs.

2. Cancellation and denial of registration of EDB products for use in quarantine fumigation of citrus, tropical fruits and vegetables on July 1, 1983. This phase-out period will allow for the development and implementation of alternative treatment methods.

3. Cancellation and denial of registration of EDB products for use in preplant soil fumigation, beehive super fumigation, vault fumigation and Japanese Beetle control, *unless* applicants or registrants modify the terms and conditions of registration as described in the following subsections. The use of EDB in quarantine fumigation is also subject to immediate cancellation unless the applicable interm terms and conditions of registration which follow are met.

The label modifications described in the subpart (a) will apply to EDB products used in soil fumigation, beehive super fumigation, vault fumigation, Japanese Beetle control, termite control and quarantine fumigation. The label modifications described in subpart (b) will apply to EDB use in connection with beehive super fumigation. The label modifications, described in subpart (d) will apply to EDB additional products used for control of termites. Subpart (e) lists additional interim label modifications and other requirements which apply to quarantine fumigation.

a. The following restrictions must appear on the label of EDB products for use in preplant soil fumigation, beehive super fumigation, vault fumigation, Japanese Beetle control, termite control, and quarantine fumigation.

i. *Warning.* EDB has caused cancer, mutagenic effects and reproductive disorders in laboratory animal tests and may present these health risks to humans.

ii. *Restricted use pesticide.* For retail sale to and use only by certified applicators or persons under their direct supervision, and only for those uses covered by the applicator's certification.

iii. *Required clothing and equipment for application.* Applicators must wear the following EDB-resistant protective clothing: butyl rubber gloves and butyl rubber, nitrile or polyethylene aprons, coveralls, and boot covers. Articles made of natural rubber must not be used. Contaminated clothing must be removed immediately, and exposed skin washed with soap and water. Gloves and boot covers must be thrown away immediately if contaminated, and after each use. Other clothing must be commercially laundered daily after use or aired for at least 24 hours. A full-face, black canister respirator must be worn at all times during application and when reentering treated sites throughout the specified reentry period.

iv. *Reentry period.* The following information must be posted clearly at

the entrances to treated areas. For preplant soil fumigation and Japanese Beetle control a sign should read: Danger. Premises fumigated with (Product Name) on (Date). Do not reenter treated area until (reentry date) or until EDB air level is less than 0.4 ppm. Wear an approved respirator if you must reenter this area before the posted reentry interval.

For quarantine fumigation centers, beehive supers, vault fumigation and termite fumigation, a sign should read: Danger. Premises fumigated with (Product Name) on (Date). Treatment period lasts until (Data). Wear a full-face, black canister respirator before reentering premises. After treatment period, open all windows, doors and vents. Reentry without a respirator is only permitted after 24 hours of aeration or when EDB air level is below 0.4 ppm.

v. *Other safety precautions.* The label must also include statements expressing the following requirements: Fumigation may take place only when personnel will not be in the areas (i.e., treated field or building) during the treatment period and the reentry period. Humans and animals must be vacated from treatment area before fumigation. EDB may not be used or stored in domestic dwellings. Soap and water must be available for washing skin or flushing eyes in case of contact with EDB. Applicators must wash hands before eating or smoking. Transferring activities (i.e., pouring) must be conducted outdoors, unless a closed transfer system is used. Spills must be cleaned up immediately. If a spill is on soil, cover with six inches of soil. If a spill occurs on other surfaces, remove EDB with an appropriate cleaning agent; Pesticide containers must be disposed of either by burying in a State-approved pesticide disposal site or by returning them to a container reprocessor. Containers or equipment made of aluminum, magnesium, or their alloys must not be used, because EDB will corrode them.

b. In addition to containing the above-mentioned restrictions the label of EDB products registered for fumigation of beehive supers must be modified to include the following restrictions.

i. *Use directions.* Hives and/or combs (supers) must be placed in a gas-tight room or under a gas-tight covering such as a polyethylene tarpaulin held down with sand-filled "snakes." All windows, doors and vents must be sealed. All persons not involved with the fumigation must be vacated from the building.

ii. *Prevention to food residues.* To avoid possible contamination of honey or honeycombs, treatments is limited to use on clean supers in storage and is prohibited on other sites.

c. In addition to including the restrictions mentioned in subsection a, the labels of EDB products registered for use in Japanese Beetle control must be modified to include the following requirements. The USDA/APHIS manual should be revised to contain requirements consistent with the label restrictions described below.

i. *Grass sod.* Treated sod must be covered with a heavy plastic or tarp during the treatment period to ensure an efficacious treatment and to minimize air exposures. The tarp must be aired before re-use.

ii. *Bareroot plants.* The proper method for disposing of the used EDB-water mixture must be specified.

iii. *Balled or containerized plants.* The "enclosed place" into which plants are placed after treatment must be posted with signs indicating the minimal reentry information described previously. Proper disposal methods must be described.

iv. *Potting and bench soil.* Soil must be covered with plastic or heavy tarp for duration of the treatment period.

v. *Beds and other uses.* Soil must be covered with plastic or heavy tarp for duration of the treatment period.

vi. *For all above uses.* The APHIS Manual states that for balled or containerized plants, treatment is approved only when beetle grubs (larvae and pupae) are present.

d. In addition to the restrictions required under subsection a, the terms and conditions of registration for EDB products used in the control of termites must contain the following modifications.

i. *Certified applicators.* Fumigation may be conducted only by certified *commercial* applicators.

ii. *Protective clothing.* Same as stated in subpart a.

iii. *Posting.* The applicable requirements for termite control should be posted continuously until reentry is permitted.

iv. *Use directions for drywood termites.* Person not involved with the fumigation must leave the premises before fumigation. Holes of appropriate size and spacing must be drilled and the recommended dosage of EDB injected into these holes using a calibrated syringe or like device. Holes must be sealed immediately and permanently.

v. *Use directions for subterranean termites.* Persons not involved with the fumigation must leave the premises before fumigation. Use is not permitted under slabs which contain air ducts. Recommended dosage must be injected through holes drilled in infested concrete slab structures. Holes must be sealed immediately and permanently.

vi. *Ventilation.* During and after fumigation, all doors, windows and vents in the treatment area and connected buildings must be opened.

e. In addition to including the restrictions mentioned in subsection a, EDB labels for quarantine fumigation of citrus, tropical fruits, and vegetables must be modified to require that the EDB concentration in air does not exceed 0.4 ppm (15 min. avg.) in warehouses where treated fruit or vegetables are stored. EDB labels must also be modified to require the following notice be posted prominently in warehouses containing EDB-treated fruits or vegetables: WARNING. Fumigated commodities may emit harmful ethylene dibromide vapors. If EDB air levels exceed 0.4 ppm wear a full-face, black canister respirator.

In order for fumigation centers or warehouses to meet the 0.4 ppm standard, the following measures are recommended. If these measures are not adequate to meet the standard, additional measures may be implemented.

—Install closed dispensing system (EDB-resistant tubing with soldered connections), including an air coupling (with which to purge the line before opening it), and a pressure relief valve. Valves would be designed for handling EDB.

—Install an air monitoring device in fumigation centers and warehouses with an IR detector connected to an alarm and calibrated to be triggered if the EDB air levels exceed 0.4 ppm.

—Adjust the ventilation system so that there is greater pressure in the fumigation center than in the fumigation chambers.

—Train all applicators and warehouses employees in all aspects of fumigation procedures, protective equipment, safety precautions and emergency plans.

—Test fumigation chambers for leaks before the USDA inspector approves a fumigation permit.

—Restart exhaust fan after opening chamber door to move EDB vapors away from workers.

—Monitor personnel in both fumigation centers and warehouses to detect EDB exposure levels on a scheduled basis.

—Post operating instructions and emergency procedures in both fumigation centers and fruit warehouses.

—Replace cardboard fruit containers with a bulk loading sytem.

IV. Procedural Matters

This Preliminary Notice of Determination notifies the United States Department of Agriculture, the Scientific Advisory Panel, pesticide registrants and other interested persons and provides these entities and individuals with the opportunity to comment on these determinations.

As discussed in Unit II of this Notice, the Agency's decision to initiate the regulatory action described in Unit III must be referred for review to the Secretary of Agriculture and the Scientific Advisory Panel. The EPA Position Document 2/3, setting forth in detail the reasons and factual bases for the regulatory actions which the Agency proposes, and this Notice of Determination are being transmitted immediately to the Secretary of Agriculture and the Scientific Advisory Panel for comments. The Agency also will offer registrants and other interested persons an opportunity to comment on the bases for the Agency's action by making copies of the PD 2/3 available upon request. Interested persons may receive copies of the documents by communicating their requests to Richard Johnson, Project Manager, Special Pesticide Review Division, Office of Pesticide Programs, EPA (TS–791), Room 709, Crystal Mall II, 1921 Jefferson Davis Highway, Arlington, Virginia 22202, (703) 557–7451. Registrants and other interested persons have the same 30-day period in which to submit comments that the statute provides for comments from the Secretary of Agriculture and the Scientific Advisory Panel.

All comments on the proposed actions should be sent to the Document Control Office, Management Support Division, EPA (TS–793), Room E–447, 401 M Street SW., Washington, D.C. 20460. In order to facilitate the work of the Agency and of others inspecting the comments, registrants and other interested persons should submit three copies of their comments. The comments should bear the identifying notation [OPP 30000/25B] and should be submitted by January 9, 1981.

After completion of these review procedures, the Agency will consider the comments received and publish an analysis of them, together with any changes in the regulatory actions announced in this Notice which it determines are appropriate. Until this final review phase is concluded, it is not necessary for registrants or other interested persons to request a hearing to contest any regulatory action resulting from the conclusion of this RPAR.

Dated: December 2, 1980.

Steven D. Jellinek,

Assistant Administrator for Pesticides & Toxic Substances.

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